Supplementary data for:

Cardiac catheterisation: Radiation doses and lifetime risk of malignancy

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ADDITIONAL METHODOLOGICAL DETAIL

The diamentor used to measure the DAP samples a cross-section of the X-ray beam and is calibrated in situ using procedures traceable to national standards.(1) A computer was used to read and reset the diamentor remotely. The recorded DAP values were corrected to a standard patient size, as described previously.(2) We estimated the risk of malignancy for each specific examination from the ED values.(3) Published reports indicate an estimate of 2.5% per Sievert (2.5×10^{-2} Sv^{-1}or 1 in 40 000 per milliSievert) additional lifetime risk of fatal cancer for a population between the ages of 40 and 60 years(4), and this figure has been used for comparative purposes here. Above the age of 60, this risk factor decreases by up to 0.8% per Sievert (5), so for some individual patients the calculated risks will be an over-estimate. For children and younger adults, the derived risks will be an underestimate.

A description of the projections and conversion factors is given in Table S1. In addition to the primary analysis, we also compared the DAP values with patient age, gender, weight and the experience of the operators. Patients undergoing immediate percutaneous coronary intervention were excluded from the study.

Diagnostic group 1 A.COR:

This group involved imaging only the left and right native coronary arteries. A total of 5 views for the left coronary system and 3 views for a dominant right coronary artery were routinely used (Table S2). Additional views were taken only when required.

Diagnostic group 2 A.LVC:

This group involved imaging the native coronary arteries as well as imaging the left ventricle. In the vast majority a single right anterior oblique examination was performed for left ventriculography. Occasionally, an additional left anterior oblique view was performed at the operator's discretion.

Diagnostic group 3 RH.LVC:

This group involved imaging the native coronary arteries, the left ventricle, and occasionally the right ventricle and the pulmonary arteries. The procedure required screening to monitor passage of catheters to the pulmonary arteries.

Diagnostic group 4 A.LAC:

This group involved imaging the native coronary arteries, the left ventricle and the aorta.

Diagnostic group 5 A.CAB:

This group involved imaging the native coronary arteries, the left ventricle as well as coronary arterial and/or venous bypass grafts. At least two views of all grafts were taken, with single views of occluded grafts.

Diagnostic group 6 A.CAC:

This group involved imaging the native coronary arteries, the left ventricle, the aorta and coronary artery bypass grafts.

In patients with left main stem disease and occluded vessels only limited views were taken depending on operator preference and the information being sought. All images were acquired at 12.5 frames per second with a field size of 17 cm except left ventriculography and aortography. These images were acquired at 25 frames per second with a field size of 23 cm. Coronary angiography was performed with hand injection of contrast.

STATISTICAL ANALYSIS

The SPSS statistical software package (version 10.1) was used to perform all statistical calculations. Continuous variables are expressed as numbers (percentages) and mean ± standard deviation (median). For all tests, a value of $p<0.05$ was considered statistically significant. Spearman's correlation coefficient was used to correlate DAP with age and weight. An independent sample's t-test was used to compare DAP in male and female patients and experienced and trainee operators between the different groups.

ADDITIONAL RESULTS

The baseline characteristics of study patients are shown in table S3. The average age of the study patients was 61.4±10.5 years and 68% were male. The ED in different diagnostic groups is shown in figure 1.

Other analysis

We correlated the DAP with age and weight. There was a significant correlation between patient weight and the DAP (correlation coefficient 0.4, $p=<0.0001$). However, there was no significant correlation between age and the DAP (correlation coefficient 0.02, $p=0.1$). The differences in the DAP by gender were significant for each individual diagnostic group for all studies [men vs. women: 25.2±15.2 vs. 20.6±14.4, $p=<0.0001$). This is explained by the fact that men were heavier than women (83.1± 13.8 kilograms vs. 70.7±13.3 kilograms).

After adjusting for patient's weight, there was no significant difference in the DAP between experienced operators (consultants) and trainee operators (registrars) in all groups except in group A.LVC where the consultants had significantly higher DAP readings compared to the registrars (22.2±11.8 vs. 21.2±1.9, $p=0.009$) and in group RH.LVC (28.3±13.6 vs. 36±24.6, $p=0.006$) where the experienced operators had significantly lower DAP readings compared to trainee operators.

ADDITIONAL DISCUSSION

The potential harmful effects of radiation are documented along with permitted recommended safe dose limits to staff (International Commission on Radiological Protection-ICRP).(6) Deterministic effects are those in which the number of cells lost in an organ or tissue is so great that there is a loss of tissue function.(7-9) The harm will not occur below a threshold and above this the severity of the effect will increase with dose. Skin erythema and ulceration are examples of deterministic effects. Stochastic effects occur if an irradiated cell is modified rather than killed and then goes on to reproduce. The result may be the manifestation of a cancer after a prolonged and variable delay called the latent period. Stochastic effects do not appear to have a threshold and the probability of the effect occurring is related to the radiation dose. The risk of long-term stochastic effects (e.g. cancer, leukaemia) is usually assessed by effective dose which makes some allowance for the properties of the radiation concerned and for non-uniform distribution of radiation over the body.(4)

The United States Food and Drug Administration(10), the World Health Organisation(11), the ICRP(12) and the International Electrotechnical Commission have published recommendations on how to avoid radiation injuries. In addition, the International Electrotechnical Commission has published a report on general safety and radiation protection entitled, "Particular requirements for the safety of X-ray equipment for interventional procedures"(13) which includes general safety and radiation protection aspects.

Current recommendations are to limit occupational dose to 100 mSv over five years (not to exceed 50 mSv in any one year) and doses to the public to 1 mSv per year(14). A recent study demonstrated that a cumulative radiation exposure of 100 mSv would lead to a 9.7% (1.4 to 19.7%) increased mortality from cancers excluding leukaemia and a 5.9% (-2.9 to 17%) increased mortality from all cancers excluding leukaemia, lung, and pleura compared with background rates. This study was a large study of workers in the nuclear industry in 15 countries(15).

The DAP measurements have been widely used in previous studies either as a means of comparison of radiation dose or as a step to estimating risk(3). Our results on the DAP measurements and ED are comparable to previous studies. However this is the first study to describe in detail the hypothetical additional lifetime risk of malignancy in patients undergoing different radiological cardiac diagnostic procedures. This study also provides diagnostic reference levels as recommended by the International Commission on Radiation Protection (ICRP 60)(4), as directed in Europe by Council Directive 97/43/Euratom and as implemented in the United Kingdom by the Ionising Radiation (Medical Exposure) Regulations 2000.

In a previous study by Clark et al, the mean DAP reading for coronary angiography (n=117) was 14.24 Gy cm^2 and for an additional left ventriculography (n=944) the DAP was 20.26 Gy cm^2. They did not demonstrate a significant increase in the DAP for coronary artery bypass graft imaging and aortogram (n=53). They did however demonstrate an increase in the screening time for right heart imaging (n=90) with no significant increase in the radiation dose. This study did not calculate the effective dose nor the patient risk of malignancy(16). In our study the slightly higher increase in the DAP for patients undergoing coronary angiography alone was not statistically significant from those who underwent left ventriculography examinations. In contrast to the study of Clark et al, we have also demonstrated that additional aortography to the graft and left ventriculography significantly increases the DAP values.

In another study by Zorzetto et al, the patients' means DAP was 55.9 Gy cm^2 for 39 diagnostic coronary angiography procedures. Their study measured a cumulative DAP for all different diagnostic cardiac catheterisation procedures including ventriculography, bypass graft imaging and right heart catheterisation. Their study did not calculate the effective dose nor the risk to patients and only considered a small cohort of patients undergoing diagnostic cardiac catheterisation (n=79)(17).

Leung et al(5), calculated a mean DAP value of 14 Gy cm^2 and an effective dose of 3.1 mSv for 90 coronary angiography examinations. In another study of 29 coronary angiography procedures by Betsou et al, the mean DAP and ED for patients undergoing coronary angiography was 30.4 Gy cm^2 and 5.6 mSv respectively. In their study, a conversion factor of 0.183 mSv/Gy cm^2 estimated with the help of a Rando phantom method was used to calculate the ED from the DAP values(18).

Vano et al (19) in a study of patients undergoing coronary angiography recorded a mean DAP of 46 Gy cm^2. This value is significantly higher than our value. This value was obtained from 2 different X-ray systems (Philips Optimus M-200 and Philips Integris HM3000; Philips Medical Systems, Best, The Netherlands). This study consisted of procedures performed from 1985 to 1999. The procedures carried out before 1992 were performed with a different X-ray system (Compagnie Generale de Radiologie, GE-CGR). The cardiologists during this period were not specifically trained in radiation protection. Also the frame rates were set at 25 frames per second. In the new systems, the filming rate was 12.5 frames per second and the fluoroscopy was pulsed. These factors probably explain the higher DAP values obtained in their study.

The different DAP values obtained in different studies indicates that there are a number of factors affecting patient dose in addition to the type of procedure. These include the type of X-ray system used, the acquisition frame rate and the radiation protection training for cardiologist. There are a number of radiation protection training courses organised by IRMER in the United Kingdom which enable the trainees and cardiologists working in the cardiac catheter laboratory to familiarise themselves with the radiation protection issues. The differences found in DAP values between consultant staff and trainees might be a chance observation but could be accounted for by the fact that interventional cardiologists take additional views at times to determine whether there is a reasonable chance of a successful interventional approach to the patient's management or that consultants in general might perform the diagnostic procedure in more challenging cases but that their additional experience reduces the exposure required for combined right and left heart catheterisation.

Comparison with other risks in this patient population

In a previous report (20), the mortality associated with cardiac catheterisation and coronary angiography was 0.11%. The incidence of total major complications was 1.7%. This included myocardial infarction (0.05%), cerebrovascular accident (0.07%), arrhythmia (0.38%), vascular complications (0.43%), contrast reaction (0.37%), haemodynamic complications (0.26%), perforation of heart chamber (0.03%) and other complications (0.28%). In another study (21), the risk of sudden death was 6.7 times higher in patients with coronary heart disease (CHD) than in those without CHD. In that study, 40% of sudden deaths occurred in the 4% of the general population with overt coronary heart disease. Living in Cornwall (United Kingdom) has an additional radiation of 7 mSv per year and a flight to the USA has an additional radiation dose of 40-50 uSv (22). Typical effective dose for a chest X-ray (PA) is 0.02 mSv and for CT angiography is 10 mSv. MR coronary angiography does not involve radiation. Nuclear medicine involves 8-20mSv of radiation(22). In coronary angiography, the number of runs and frame rate contribute to the radiation dose rather than the screening time.

Although the risks associated with coronary heart disease itself and coronary angiography are relatively high compared to the hypothetical additional lifetime risk of malignancy in patients undergoing different radiological cardiac diagnostic procedures, it is still important to keep the doses and risks as low as practicable.

The radiation dose to the patient can be adjusted by opening the iris on the television camera, allowing a lower increase in beam intensity and also by using flat panel detectors which have more sophisticated controls. Scatter is an important phenomenon and may form well over half the image content in large patients. To minimise it, an air gap between the patient and the detector can be used. This simple procedure can significantly reduce radiation exposure without seriously affecting image quality(23). In addition, the need for left ventriculography can be questioned if the relevant information has already been acquired from non-invasive investigations.

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Table S1: Description of projections and conversion factors

Examination	Projections	% of total DAP from specific projection	Conversion factor ($mSv/Gy\ cm^2$)
A.COR, A.LVC, RH.LVC, A.CAB	RAO*	60%	0.230
	LAO**	40%	0.205
A.LAC, A.CAC	RAO*	70%	0.230
	LAO**	30%	0.205

DAP: dose-area product, RAO: right anterior oblique, LAO: left anterior oblique.

***6 RAO projections:**

4 left coronary artery views (RAO 10, RAO 35, RAO caudal, RAO cranial / Postero Anterior)

1 right coronary artery view (RAO)

1 left ventriculography view (RAO 30)

**** 4 LAO projections:**

2 left coronary artery views (LAO caudal, LAO cranial)

2 right coronary artery views (LAO, LAO cranial)

Table S2: Common X-ray projections used during cardiac catheterisation

Artery	Projections	Occasional views
Left Coronary artery	Postero-anterior	PA caudal
	RAO straight	PA cranial
	RAO caudal	RAO cranial
	LAO cranial	Lateral
	LAO caudal	
Right coronary artery	LAO straight	LAO cranial
	RAO straight	Lateral
Ventriculography/aortography	RAO 30	

PA: Postero-anterior view

RAO: right anterior oblique view

LAO: left anterior oblique view

Table S3: Baseline characteristics of study patients

Patient characteristics	Total n = 4398
Male	2985 (68%)
Weight (kilograms)	79.1 ± 14.8
Age (years)	61.4 ± 10.5
Systolic BP (mm Hg)	142.5 ± 44
Diastolic BP (mm Hg)	69.4 ± 12.5
Previous MI	1121 (25%)
Previous PCI	312 (7%)
Previous CABG	279 (6.3%)

Data are presented as number (%) and mean ± standard deviation

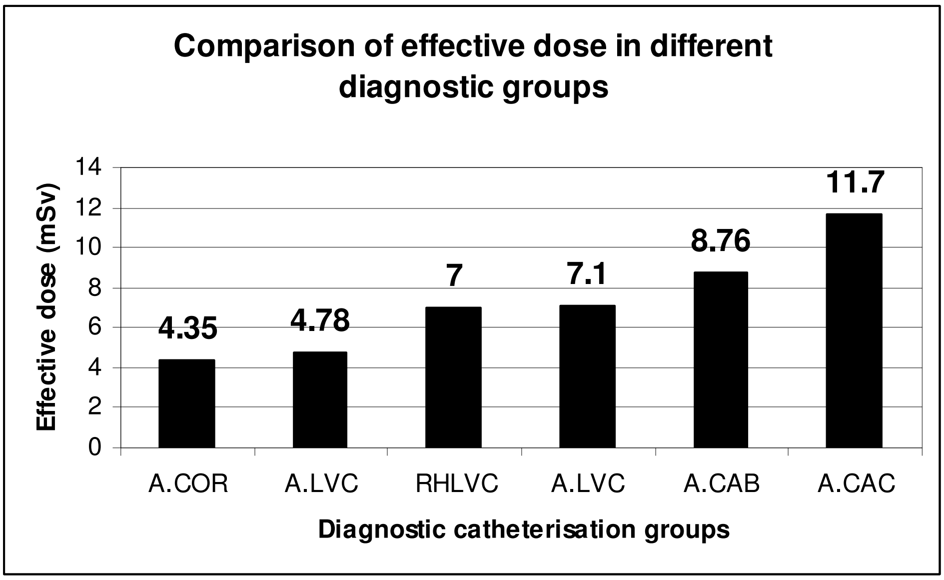
BP: blood pressure

MI: myocardial infarction

PCI: percutaneous coronary intervention

CABG: coronary artery bypass graft

Figure 1:


Comparison of effective dose in different diagnostic groups
Effective dose (mSv)
14
12
10
8
6
4
2
0
4.35
4.78
7
7.1
8.76
11.7
A.COR
A.LVC
RHLVC
A.LVC
A.CAB
A.CAC
Diagnostic catheterisation groups